DEPARTMENT OF HEALTH & HUMAN SERVICES

APR 15 1999

Food and Drug Administration
Rockville MD 20857

8118 '99 APR 19 P1:31

The Honorable Joseph R. Pitts
Member, U.S. House of Representatives
50 North Duke Street
Courthouse, 5th Floor
Lancaster, Pennsylvania 17602

Dear Mr. Pitts:

Thank you for your letter of March 24, 1999 on behalf of Ms. Kirsten Laukhuff, regarding dietary supplements containing ephedrine alkaloids. Ephedrine alkaloids are amphetamine-like compounds with potentially strong stimulant effects on the cardiovascular (heart and blood vessels) and nervous systems. The ephedrine alkaloids in dietary supplements are naturally occurring stimulants and usually are derived from one of several species of herbs of the genus Ephedra, sometimes called Ma huang or Chinese Ephedra.

On June 4, 1997, the Food and Drug Administration (FDA or the Agency) published a proposed rule in the Federal Register (FR) regarding the formulation and labeling of dietary supplements containing ephedrine alkaloids. In the proposed rule, the Agency is proposing:

- to make a finding, which will have the force and effect of law, that a dietary supplement is adulterated if it contains 8 milligrams (mg) or more of ephedrine alkaloids per serving, or if its labeling suggests or recommends conditions of use that would result in intake of 8 mg or more in a 6-hour period or a total daily intake of 24 mg or more of ephedrine alkaloids;

- to require that the label of dietary supplements that contain ephedrine alkaloids state, "Do not use this product for more than 7 days";

- to prohibit the use of ephedrine alkaloids with ingredients, or with ingredients that contain substances, that have a known stimulant effect (e.g., sources of caffeine or yohimbine), which may interact with ephedrine alkaloids;

- to prohibit labeling claims that require long-term intake to achieve the purported effect (e.g., weight loss and body building);

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- to require a statement in conjunction with claims that encourage short-term excessive intake to enhance the purported effect (e.g., energy) that, "Taking more than the recommended serving may result in heart attack, stroke, seizure or death"; and

- to require specific warning statements to appear on product labels.

The proposal also articulates FDA's policy that products marketed as alternatives to illicit street drugs are drugs, not dietary supplements.

FDA proposed this rule in response to serious illnesses and injuries associated with the use of dietary supplement products which contain ephedrine alkaloids and in response to the Agency's investigations and analyses of these illnesses and injuries. Reported adverse events range from episodes of high blood pressure, irregularities in heart rate, insomnia, nervousness, tremors, and headaches, to seizures, strokes, and death. As of January 1997, FDA had received over 800 reports of adverse events associated with the use of more than 100 different dietary supplement products which contained, or were suspected of containing, ephedrine alkaloids. The adverse events reports showed consistent patterns of illness and injury among otherwise healthy individuals and those with underlying diseases or conditions. FDA continues to receive additional reports of adverse events associated with the use of these products.

The proposed measures were developed based on FDA's review of its adverse event reports, the scientific literature, and public comments reviewed by the Agency, including comments generated by an October 1995 advisory working group public meeting and an August 1996 public meeting of FDA's Food Advisory Committee. These experts suggested a number of steps the Agency might take to reduce injuries associated with the use of dietary supplements containing ephedrine alkaloids. If implemented, the proposed rule will reduce the risk of adverse events for consumers who use these products.

FDA allowed a 75-day comment period on the proposed rule. On September 18, 1997 (62 FR 48968), that comment period was reopened for an additional 75 days until December 2, 1997. FDA invited written comments on the proposal from the public and industry. All comments received will be reviewed and considered by the Agency in developing the final rule.

We hope this information is helpful. If we may be of any further assistance, please let us know.

Sincerely,

Kathryn S. Hudson

for Melinda K. Plaisier
Interim Associate Commissioner
for Legislative Affairs

cc: Dockets Management Branch
(Docket #95N-0304)

JOSEPH R. PITTS
16TH DISTRICT, PENNSYLVANIA

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PLEASE RESPOND TO:

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☐ 36 WEST LANCASTER AVENUE
DOWNINGTOWN, PA 19335
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☐ LANCASTER CO. COURTHOUSE
50 NORTH DUKE STREET
LANCASTER, PA 17602
(717) 393-0667

March 24, 1999

Ms. Diane Thompson
Deputy Associate Commissioner for Legislative Affairs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Ms. Thompson:

The attached communication is sent for your consideration. Your investigation of the statements contained therein would be helpful. In addition, I would greatly appreciate any information necessary to make a satisfactory reply to my constituent.

Thank you for your cooperation in this regard. I look forward to hearing from you at your earliest opportunity.

Please respond to my Lancaster office: 50 North Duke Street
Courthouse, 5th Floor
Lancaster, PA 17602
(717) 393-0666

Cordially,

Joseph R. Pitts
Member of Congress

JRP/jmr
Enclosure

No 99-2120

TO THE MEMBERS OF THE SENATE AND HOUSE OF REPRESENTATIVES:

We need your help. The Food and Drug Administration has proposed a rule (62FED.REG.30678) that would deny our right to purchase natural dietary supplements which contain the natural herb Ma Huang. This rule would unduly restrict the levels of naturally occurring ephedrine alkaloids found in Ma Huang to a level that would render these dietary supplements useless to the consumer. There are currently approximately Five Million adult Americans who regularly consume dietary supplements containing Ma Huang, which has been used safely throughout the world for over 5,000 years.

The FDA has based their proposed rule on anecdotal information. However, the FDA has admitted that anecdotal information "cannot be used to calculate incidences or estimates of risk." Additionally, we strongly believe that the proposed rule violates the 1994 Dietary Supplement Health and Education Act, which Congress passed to regulate outrageous and unnecessary actions by the FDA regarding dietary supplements.

We urge you to contact the FDA and stop this unnecessary and illegal action on their part. We are writing you on behalf of ourselves and the millions of other Americans who safely use these products on a daily basis. We need our voices to be heard and we are asking you, our elected officials, to make our voices heard.

Sincerely,